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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,200	01/23/2001	Ernst Peter Rieber	028622/0103	1983

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,200	RIEBER, ERNST PETER	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/3/05 and 1/12/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-11,16,17,30,41-43,45 and 58-63* is/are pending in the application.

4a) Of the above claim(s) *30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-11,16,17,41-43,45 and 58-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 10/03/05 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendments and remarks, filed 1/12/06, have been entered.

2. Claim 30 stands withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 1-6, 8-11, 16, 17, 41-43, 45, and 58-63 are under examination.

3. In view of Applicant's amendments and remarks, the previous rejections under 35 U.S.C. 112, second paragraph, have been withdrawn. Additionally, the previous rejection under 35 U.S.C. 112, first paragraph, for the recitation of antibody fragments capable of binding epitope has also been withdrawn, as well as the previous rejections under 35 U.S.C. 112, first paragraph, for the introduction of new matter into the claims.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 6, 8-9, and 16-17 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

A set forth previously, there is insufficient written description to show that Applicant was in possession of the "chemically modified derivative" antibody recited in the claims.

Applicant's arguments, filed 1/12/06, have been fully considered but they are not persuasive. Applicant argues that adequate support for the term is found at pages 9-12 of the specification.

The *entire* teaching of the specification regarding a "chemically modified derivative is "The antibody of the invention can be, e.g., a monoclonal antibody, polyclonal antibody, chimeric antibody, humanized antibody, bispecific antibody, synthetic, antibody, antibody fragment such as Fab, Fv or scFv fragments etc., or a chemically modified derivative of any of these" (page 9). There are no examples nor any additional description. Accordingly, it remains the Examiner's position that said derivatives have been inadequately described.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 6, 10, 16-17, 41-43, and 45, stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 93/04187 (of record).

As set forth previously, WO 93/04187 teaches a monoclonal antibody composition which reacts with human DCs and not other PBMCs, a continuous stable cell line (a hybridoma), and a method for preparing said antibody (see particularly pages 2, 5, 20, and 26). The reference also teaches a pharmaceutical composition (see particularly page 13), a diagnostic composition (see particularly page 13), and an invention that could be considered a "kit", i.e., an antibody and ligands (see particularly page 14).

Applicant's arguments, filed 1/12/06, have been fully considered but they are not persuasive. Applicant argues that because CD3 is found on a subpopulation of MRC OX-62$^+$ cells, and the specification discloses that CD3 can be found on other PBMCs, the antibody of the instant claims is not "consistent with WO 93/04187".

The reference unequivocally states, "All cells labeled with OX-62 mAb had a dendritic cell morphology". Accordingly, it would appear that the antibody labeled a CD3$^+$ DC subpopulation.

7. The following are new grounds for rejection.

8. Claims 1-6, 8-11, 16, 17, 41-43, 45, and 58-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the specification provides insufficient evidence that the antibody of the instant claims is capable of binding DCs and not other PBMCs.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. With these teachings in mind, an enabling disclosure, commensurate in scope with the breadth of the claimed invention, is required.

A review of the relevant art reveals that the antibody disclosed in the instant specification, M-DC8, is not DC-specific. As taught by de Baey et al., M-DC8 stains a subset on

monocytes that are capable of developing into DCs (see particularly page 1647). Note that monocytes are not "a DC population of a maturational stage between immature and mature", indeed, monocytes are not DCs at all. The specification discloses two additional antibodies, D-DC8.1 and D-DC8.2. All that is disclosed regarding these antibodies is that they stain cell populations in much the same way as does M-DC8 (page 69). Accordingly, in the absence of any additional disclosure, it must be assumed that these antibodies also bind monocytes. Given that the specification discloses *no* examples of the claimed antibody, the production of said antibody must be considered unpredictable and requiring of undue experimentation.

9. Claims 1-6, 8-11, 16, 17, 41-43, 45, and 58-63, are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) an antibody which binds an epitope on DCs comprising a DC population of a maturational stage between immature and mature DCs and does not bind with other PBMCs (Claims 1 and 17).

B) an antibody capable of binding to said epitope (Claim 6).

C) an antibody … wherein the DCs are selected from the group consisting of $CD64^-$, $CD33^+$, $CD45RA^+$, $CD11c^+$, $p55^-$, and $CD16^+$ (Claim 4).

D) a generic antibody comprising the limitations of Claims 58-63.

Regarding A) and B), the specification does not disclose and antibody that binds.

Regarding C), the specification discloses only a DC comprising all of these characteristics and not a DC comprising just one of them. Further, the specification discloses a DC "mostly" $CD16^+$.

Regarding D) Applicant points to Examples 11 and 12 and Figures 9 and 10 in support. The Examples and Figures, however,

disclose only specific antibodies and not the generic antibodies of the instant claims. Further, it is established in Section 8, above, that even the disclosed antibodies do not meet the limitations of independent Claim 1, i.e., that the antibody binds DCs and not other PBMCs.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

12. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

5/19/06

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